

# **LASIK Quality of Life Collaboration Project (LQOLCP)**

## **FDA/NIH/DOD**

**Frederick L. Ferris III, M.D.**

**Director**

**Division of Epidemiology and Clinical Research and  
Clinical Director, NEI/NIH**



## Financial Disclosure

- Bausch and Lomb - P

# **Questionnaire – Future Research**

**» Assessment of Current LASIK Results**

**» Long Term Results**

**» More Information – Adverse Experiences**

# Controversy Exists

- » **Some say “Highly Successful Procedure”**
- » **Others say “Very Risky Procedure”**
- » **Example of Ascertainment Bias?**

# **LASIK Surgeon sees: Visual Acuity**

**» 20/20 or Better UCVA at 3 Months**

- >95% of Subjects Binocularly**
- >90% of Subjects Monocularly**

**» Loss of  $\geq 2$  lines of BCVA**

- 0.2% of eyes**

# **LASIK Activist Sees: Selected Population**

## **» People with Adverse Experiences**

- Blurred Vision**
- Halos, Glare, Starbursts and Ghosting**
- Dry Eye**
- Depression/Anxiety and**
- Flap Dislocation and Others**

**» Even if only 1% (1% of ~20M\* = 200,000)**

**\*Rough Estimate from Quallsight and FDA current yearly estimates.**

# Dry Eyes

## » Staining

- Up to 3% of eyes had corneal staining of Oxford grade 2 or more at 3 Months

## » Symptoms

- Up to 30% of subjects developed new dry eye symptoms
- 3% of subjects worsened by 2 or more levels of OSDI from Preop to 3 Months

Many Eye Drops now  
Advertising to Treat:  
“LASIK Dryness”

Market Size??





# **New Questionnaire**

## **New Opportunity**

- » Assess complex visual symptoms**
- » Capture preoperative expectations as well post-operative satisfaction**
- » Identify Long Term Adverse Experiences**

# **Careful Future Studies can Provide Accurate Rates**

- » Functional Satisfaction**
- » Post-op Adverse Experiences**
- » Long Term Adverse Experiences**
- » Provide These Rates to Inform all  
Prospective Patients**

- **Steering Committee**

- » Barbara Berney
- » Matthew Caldwell
- » Janine Clayton
- » Barbara Hawkins
- » Donald Patrick
- » Donna Peterson
- » Michael Raizman
- » Christopher Rapuano
- » Michael Twa
- » Jayne Weiss

- **PROWL-2 Investigators**

- » Kraig S. Bowers
- » Daniel Durrie
- » Edward Manche
- » Vance Thompson
- » William Zeh

- **PROWL-1**

- » Donna Murdoch
- » Myah Mirzaoff

- **Study Group**

- » Rachel Bishop
- » Malvina Eydelman
- » Frederick Ferris
- » Gerry Gray
- » Keri Hammel
- » Ron Hays
- » Gene Hilmantelbb
- » Elizabeth Hofmeister
- » Danica Marinac-Dabic
- » Lawrence Park
- » Eva Rorer
- » Robert Sperduto
- » Michelle Tarver
- » Susan Vitale
- » Pat Wilkinson

- **EMMES Corporation**

- » Jenna Cohen
- » Jeanine May
- » Steve Reise (subcontractor)
- » Karen Spritzer (subcontractor)